(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 753 320 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
15.01.1997 Bulletin 1997/03

(51) Int. Cl.[6]: A61M 16/00

(21) Application number: 96109790.4

(22) Date of filing: 18.06.1996

(84) Designated Contracting States:
CH DE ES FI GB IT LI NL SE

(30) Priority: 10.07.1995 SE 9502543

(71) Applicant: Lachmann, Burkhard, Prof.
26123 Oldenburg (DE)

(72) Inventors:
- Lachmann, Burkhard, Prof. Dr.
26123 Oldenburg (DE)
- Rajan, Govinda
Rochelle Park, New Jersey 07662 (US)
- Böhm, Stephan
51429 Bergisch Gladbach (DE)

(74) Representative: Blumbach, Kramer & Partner
Patentanwälte
Radeckestrasse 43
81245 München (DE)

(54) Artificial ventilation system

(57) An artificial ventilation system and a method for controlling the artificial ventilation system for obtaining an optimized artificial ventilation of a lung system of a patient is described. Optimal artificial ventilation is obtained when the blood system of the patient is maximally oxygenated and, at the same time, the negative influence on the cardio-pulmonary system is minimized. The ventilation system comprises a gas delivery unit (2) for delivering controllable inspiration pulses to a patient (4), a monitoring unit (14) for measuring at least one parameter related to the function of the lung system, such as a blood gas analyser, and a control unit for determining an optimal peak inspiratory pressure and pressure amplitude for the inspiration pulse based on the measured blood gas parameter.

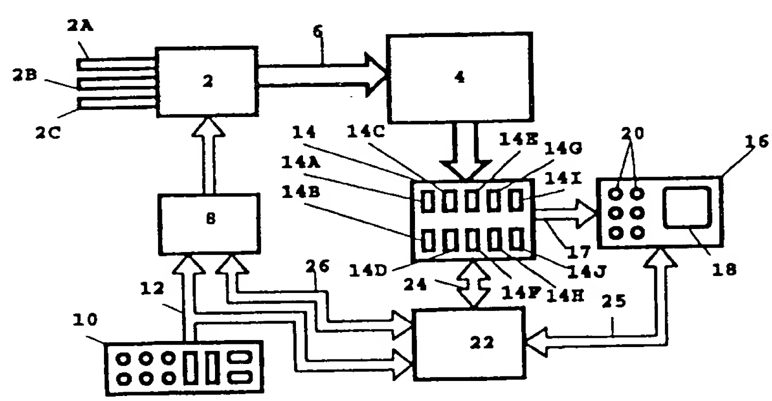

FIG 1

EP 0 753 320 A1

cies treated (human or animal), age (neonatal, infant, child, adult) and kind of illness. In the most straightforward realisation of the artificial ventilation system according to the invention, it could be adapted to automatically treat at least 90-99% of all adults, and require overriding settings from a physician in the remaining cases (before they too can be treated automatically).

Claims

1. An Artificial ventilation system comprising a respiratory gas delivery unit (2), connectable to a lung system of a living being (4) for generating and delivering controllable inspiration pulses (78) of respiratory gas to the lung system, a regulating unit (8) connected to the respiratory gas delivery unit (2) for controlling the generation and delivery of inspiration pulses (78; 116A-116F; 146A-146F) based on a control signal supplied to the regulating unit (8), a monitoring unit (14, 14A-14F) for measuring at least one parameter related to the function of the lung system and a control unit (22) connected to the monitoring unit (14, 14A-14F) for determining a change in an inspiration pulse parameter, **characterized in** that the monitoring unit (14, 14A-14F) comprises a blood gas analyser (14A) connected to the blood system of the living being (4) for measuring a blood gas parameter and the control unit (22) determines an optimal peak inspiratory pressure (PIP) and pressure amplitude for the controllable inspiration pulse (78; 116A-116F; 146A-146F) based on the measured blood gas parameter, which optimal peak inspiratory pressure (PIP) and pressure amplitude are intended to provide a sufficient oxygenation of the blood system with a minimum of negative cardio-pulmonary influence, such as barotrauma, volutrauma, overdistension and hypoxic vasoconstriction.

2. Ventilation system according to claim 1, **characterized in** that the blood gas analyser (14A) measures the partial pressure of oxygen (P_aO_2) in the blood system and the control unit (22) determines a minimum peak inspiratory pressure (PIP) and pressure amplitude, for which the measured P_aO_2 exceeds a predetermined P_aO_2 threshold value.

3. Ventilation system according to claim 1 or 2, **characterized in** that the monitoring unit (14, 14A-14F) further comprises a flow meter (14B) for measuring the flow (Φ) of respiratory gas to and/or from the lung system and the control unit (22) determines one or several of the inspiration pulse parameters: external positive end expiratory pressure ($PEEP_e$), respiration rate (RR) and inspiration/expiration time ratio (I:E ratio).

4. Ventilation system according to claim 3, **characterized in** that the control unit determines an end expiratory flow (Φ_{EE}) and a peak expiratory flow (Φ_{PE}) and determines an optimal respiration rate (RR) and/or an optimal inspiration/expiration time ratio (I:E ratio) based on the quotient between the determined end expiratory flow (Φ_{EE}) and peak expiratory flow (Φ_{PE}).

5. Ventilation system according to any of the above claims, **characterized by** a monitor screen (16, 18) connected to the monitoring unit (14, 14A-14F) for displaying measured parameters and/or connected to the control unit (22) for displaying determined inspiration pulse parameters.

6. Ventilation system according to any of the above claims, **characterized in** that the control unit (22) generates the control signal based on the determined change in the inspiration pulse parameter.

7. Ventilation system according to any of the above claims, **characterized by** a control panel (10) connected to the regulating unit (8) for providing a further control signal based on a manually entered setting of ventilation modes and/or inspiration pulse parameters, whereby a further setting on the control panel (10) determines whether the control signal or the further control signal has precedence.

8. Ventilation system according to any of the above claims, **characterized in** that the control unit (22) determines an opening pressure (P_o) of the lung system.

9. Ventilation system according to claim 8, **characterized in** that the control unit (22) determines a closing pressure (P_c) of the lung system.

10. Ventilation system according to any of the above claims, **characterized in** that the blood gas analyser (14A) measures the partial pressure of carbon dioxide (P_aCO_2) in the blood system.

11. Ventilation system according to any of the above claims, **characterized in** that the monitoring unit (14, 14A-14F) comprises a CO_2-meter (14E) for measuring the CO_2 content of expired respiratory gas and the control unit (22) determines any or several of the CO_2-parameters: end tidal CO_2, CO_2 minute production, CO_2 tidal production, ineffective tidal volume, effective tidal volume and effective ventilation.

12. Ventilation system according to claim 10 or 11, **characterized in** that the control unit (22) at predetermined intervals determines whether hypoventilation is present.

13. Ventilation system according to claim 12, **characterized in** that, when hypoventilation is present, the

control unit (22) determines a change in the peak inspiratory pressure (PIP) and/or the dead space (DS) of the artificial ventilation system for removing the hypoventilation condition.

14. Ventilation system according to any of the claims 10-13, **characterized in** that the control unit at predetermined intervals determines whether hyperventilation is present.

15. Ventilation system according to claim 14, **characterized in** that, when hyperventilation is present, the control unit determines a change in the peak inspiratory pressure (PIP) and/or the positive end expiratory pressure (PEEP) and/or the dead space (DS) of the artificial ventilation system and/or the respiratory rate for removing the hyperventilation condition.

16. Ventilation system according to any of the above claims, **characterized in** that the monitoring unit (14, 14A-14F) comprises a blood pressure meter (14D) for measuring a blood pressure of the blood system and the control unit (22) at predetermined intervals determines whether cardiovascular depression is present, and if cardiovascular depression is present, the control unit (22) will generate a cardiovascular depression signal, which cardiovascular depression signal preferably can be utilized for generating an audible/visual alarm and/or for controlling an inspiration pulse parameter.

17. Ventilation system according to any of the above claims, **characterized in** that the control unit (22) determines a new inspiration pulse parameter by iteratively changing the inspiration pulse parameter and monitoring the effect in the measured parameter(s) after a predetermined number of inspiration pulses, having the new inspiration pulse parameter, have been delivered to the lung system.

18. Method for controlling an artificial ventilation system, connectable to the lung system of a living being, **characterized by** the steps of:

a) determining an optimal ratio between inspiration time and expiration time (I:E ratio);
b) determining an optimal respiration rate (RR);
c) determining an opening pressure (P_o) of the lung system;
d) determining a closing pressure (P_c) of the lung system;
e) at intervals order a monitoring of the condition of the lung and, if necessary determine a change in an inspiration pulse delivered to the lung system;
f) ordering a change in the inspiration pulse for provoking spontaneous respiration.

19. Method according to claim 18, **characterized in** that step a) comprises the following sub-steps:

a1) reading a current I:E ratio;
a2) measuring an end expiratory flow (Φ_{EE});
a3) measuring a peak expiratory flow (Φ_{PE});
a4) calculating a EEPkΦ-ratio between the measured end expiratory flow (Φ_{EE}) and the peak expiratory flow (Φ_{PE});
a5) comparing the calculated EEPkΦ-ratio with a predetermined first EEPkΦ-threshold value;
a6) if the calculated EEPkΦ-ratio exceeds the first EEPkΦ-threshold value, determining the current I:E ratio as the optimal I:E ratio;
a7) if the calculated EEPkΦ-ratio does not exceed the first EEPkΦ-threshold value, comparing the current I:E ratio with a predetermined maximum I:E ratio;
a8) if the current I:E ratio exceeds the predetermined maximum I:E ratio, determining the current I:E ratio as the optimum I:E ratio;
a9) if the current I:E ratio does not exceed the predetermined maximum I:E ratio, comparing the current I:E ratio with a predetermined I:E ratio threshold;
a10) if the current I:E ratio exceeds the predetermined I:E ratio threshold, calculating a new I:E ratio, which is equal to the difference between the first EEPkΦ-threshold value minus the calculated EEPkΦ-ratio and the current I:E ratio and repeating the procedure from sub-step a1);
a11) if the current I:E ratio does not exceed the predetermined I:E ratio threshold, comparing the calculated EEPkΦ-ratio ratio with a second EEPkΦ-threshold value;
a12) if the calculated EEPkΦ-ratio exceeds the second EEPkΦ-threshold value, setting a new I:E ratio to be equal to the maximum I:E ratio and repeating the procedure from sub-step a1);
a13) if the calculated EEPkΦ-ratio does not exceed the second EEPkΦ-threshold value, determining the current I:E ratio as the optimum I:E ratio.

20. Method according to claim 19, **characterized in** that the first EEPkΦ-threshold value is between 30 and 40, the second EEPkΦ-threshold value is between 10 and 20 and the I:E ratio threshold is preferably between 60 and 80%.

21. Method according to any of the claims 18-20, **characterized in** that step b) comprises the following sub-steps:

b1) reading a current respiration rate (RR);
b2) measuring an end expiratory flow (Φ_{EE});
b3) measuring a peak expiratory flow (Φ_{PE});
b4) calculating a EEPkΦ-ratio between the

measured end expiratory flow (Φ_{EE}) and the peak expiratory flow (Φ_{PE});

b5) comparing the calculated EEPkΦ-ratio with a predetermined first EEPkΦ-threshold value;

b6) if the calculated EEPkΦ-ratio exceeds the first EEPkΦ-threshold value, determining the current respiration rate (RR) as the optimal respiration rate;

b7) if the calculated EEPkΦ-ratio does not exceed the first EEPkΦ-threshold value, comparing the current respiration rate (RR) with a predetermined maximum respiration rate;

b8) if the current respiration rate (RR) exceeds the predetermined maximum respiration rate, determining the current respiration rate (RR) as the optimum respiration rate;

b9) if the current respiration rate (RR) does not exceed the predetermined maximum respiration rate, comparing the calculated EEPkΦ-ratio with a second EEPkΦ-threshold value;

b10) if the calculated EEPkΦ-ratio exceeds the second EEPkΦ-threshold value, comparing the calculated EEPkΦ-ratio with a third EEPkΦ-threshold value;

b11) if the calculated EEPkΦ-ratio exceeds the third EEPkΦ-threshold value, determining a new respiration rate (RR) to be equal to the current respiration rate (RR) multiplied by a first factor and repeating the procedure from sub-step b1);

b12) if the calculated EEPkΦ-ratio does not exceed the third EEPkΦ-threshold value, determining a new respiration rate (RR) to be equal to the current respiration rate (RR) multiplied by a second factor and repeating the procedure from sub-step b1);

b13) if the calculated EEPkΦ-ratio does not exceed the second EEPkΦ-threshold value, determining a new respiration rate (RR) to be equal to the current respiration rate (RR) multiplied by a third factor and repeating the procedure from sub-step b1).

22. Method according to claim 21, **characterized in** that the first EEPkΦ-threshold value is 40, the second EEPkΦ-threshold value is 20, the third EEPkΦ-threshold value is 30, the first factor is 1.2, the second factor is 1.5 and the third factor is 2.

23. Method according to any of the claims 18-22, **characterized in** that step c) comprises the following sub-steps:

c1) obtaining the lean body weight of the living being;

c2) delivering a predetermined number of inspiration pulses having a current peak inspiratory pressure (PIP) and a current positive end expiratory pressure (PEEP);

c3) measuring the partial pressure of oxygen (P_aO_2) in a blood system of the living being;

c4) comparing the measured P_aO_2 with a predetermined P_aO_2 threshold value;

c5) if the measured P_aO_2 exceeds the predetermined P_aO_2 threshold value, determining the PIP as the opening pressure (P_o) and storing the determined opening pressure (P_o) and current PEEP;

c6) if the measured P_aO_2 does not exceed the predetermined P_aO_2 threshold value, measuring an inspiration flow (Φ) to the living being, determining a tidal volume (V_t) of supplied respiratory gas, calculating a quotient between the determined tidal volume (V_t) and the lean body weight and comparing calculated quotient with a predetermined V_t threshold value;

c7) if the calculated quotient exceeds the predetermined V_t threshold value, measuring a carbon dioxide content (CO_2 content) and comparing the measured CO2 content with a predetermined CO2 content threshold value;

c8) if the calculated quotient does not exceed the predetermined V_t threshold value or if the measured CO2 content exceeds the predetermined CO2 content threshold value, comparing the current PIP with a predetermined maximum PIP value;

c9) if the current PIP does not exceed the maximum PIP value, setting a new current PIP to be equal to the current PIP plus a first predetermined increment and repeating the procedure from substep c2);

c10) if the measured CO2 content does not exceed the predetermined CO2 content threshold value, measuring the intrinsic positive end expiratory pressure ($PEEP_i$) and comparing it with a predetermined maximum $PEEP_i$ value;

c11) if the measured $PEEP_i$ does not exceed the predetermined maximum $PEEP_i$ value, comparing the current PIP with the maximum PIP value;

c12) if the current PIP does not exceed the predetermined maximum PIP value, setting a new current PIP to be equal to the current PIP plus a second predetermined increment, setting a new current PEEP to be equal to the current PEEP plus a third predetermined increment and repeating the procedure from substep c2);

c13) if the current PIP exceeds the predetermined maximum PIP value, comparing the current PEEP with a predetermined maximum PEEP value;

c14) if the current PEEP does not exceed the predetermined maximum PEEP value, setting a new current PEEP to be equal to the current PEEP plus a fourth predetermined increment and repeating the procedure from substep c2);

c15) if the current PEEP exceeds the predeter-

mined maximum PEEP value, or if the $PEEP_i$ in substep c10) exceeds the predetermined maximum $PEEP_i$ value, or if the current PIP in substep c8) exceeds the predetermined maximum PIP value, determining whether a new maximum PIP value, a new maximum $PEEP_e$ value or a new maximum $PEEP_i$ value should be allowed;

c16) if new maxima are not allowed, determining the current PIP as the opening pressure (P_o) and storing the determined opening pressure (P_o) and current PEEP;

c16) if new maxima are allowed, setting these and repeating the procedure from substep c2).

24. Method according to claim 23, **characterized in** that the predetermined V_t threshold value is preferably between 5 and 7 ml/kg, the first predetermined increment is 2 cmH_2O, the second predetermined increment is 2 cmH_2O, the third predetermined increment is 2 cmH_2O and the fourth predetermined increment is 2 cmH_2O.

25. Method according to any of the claims 18-24, **characterized in** that step d) comprises the following sub-steps:

d1) delivering a predetermined number of inspiration pulses having a current peak inspiratory pressure (PIP) and a current positive end expiratory pressure (PEEP);

d2) measuring pressure in or near the lung system, respiratory gas flow, partial pressure of oxygen (P_aO_2) in the blood system and a CO2 content, either in expired air or in the blood system;

d3) comparing the measured P_aO_2 with a predetermined P_aO_2 threshold value;

d4) if the measured P_aO_2 does not exceed the predetermined P_aO_2 threshold value, determining the current PIP as the closing pressure (P_c) and storing the determined closing pressure (P_c) and current PEEP;

d5) if the measured P_aO_2 does not exceed the P_aO_2 threshold value, comparing the CO2 content is compared with a first predetermined CO_2 content threshold value;

d6) if the CO_2 content exceeds the first predetermined CO_2 content threshold value, comparing the current PIP with a predetermined minimum PIP value;

d7) if the current PIP exceeds the predetermined minimum PIP value, determining the tidal volume (V_t) and comparing it with a predetermined V_t threshold value;

d8) if the determined tidal volume (V_t) does not exceed the predetermined V_t threshold value, comparing the CO_2 content with a second predetermined CO_2 content threshold value;

d9) if the determined tidal volume (V_t) exceeds the predetermined V_t threshold value or if the CO_2 content does not exceed the second predetermined CO_2 threshold value, comparing the current PIP with a first PIP threshold value;

d10) if the current PIP exceeds the first PIP threshold value, setting a new current PIP to be equal to the current PIP minus a first predetermined decrement and repeating the procedure from substep d1);

d11) if the current PIP does not exceed the first PIP threshold value, comparing the current PIP with a second PIP threshold value;

d12) if the current PIP exceeds the second predetermined PIP threshold value, setting a new current PIP to be equal to the current PIP minus a second predetermined decrement and repeating the procedure from substep d1);

d13) if the current PIP does not exceed the second predetermined PIP threshold value, comparing the current PIP with a predetermined minimum PIP value;

d14) if the current PIP exceeds the predetermined minimum PIP value, setting a new current PIP to be equal to the current PIP minus a third predetermined decrement and repeating the procedure from substep d1);

d15) if the current PIP does not exceed the predetermined minimum PIP value, or if the CO_2 content in substep d5) exceeds the first predetermined CO_2 threshold value, or if the current PIP in substep d6) does not exceed the predetermined minimum PIP value, or if the CO_2 content exceeds the second predetermined CO_2 threshold value, comparing the CO_2 content with a third threshold value;

d16) if the CO_2 content exceeds the third CO_2 threshold value, comparing the current PEEP with a predetermined minimum PEEP value;

d17) if the current PEEP exceeds the predetermined minimum PEEP value, setting a new current PEEP to be equal to the current PEEP minus a fourth decrement and repeating the procedure from substep d1);

d18) if the current PEEP does not exceed the predetermined minimum PEEP value or if the CO_2 content does not exceed the third CO_2 content threshold value, determining whether a new minimum PIP value, or a new minimum PEEP value can be allowed;

d19) if new minimum values are allowed, setting the new minimum values and repeating the procedure from substep d1);

d20) if new minimum values are not allowed, determining the current PIP as the closing pressure (P_c) and storing the determined closing pressure (P_c) and current PEEP.

26. Method according to claim 25, **characterized in**

that the predetermined V_t threshold value is preferably between 5 and 7 ml/kg, the first predetermined PIP threshold value is preferably between 30 and 45 cmH_2O, the second predetermined PIP threshold value is preferably between 20 and 30 cmH_2O, the first predetermined decrement is 3 cmH_2O, the second predetermined decrement is 2 cmH_2O, the third predetermined decrement is 1 cmH_2O and the fourth predetermined decrement is 2 cmH_2O.

27. Method according to any of the claims 18-26, **characterized in** that step e) comprises the following sub-steps:

e1) measuring pressure, CO_2 content, P_aO_2 and blood pressure;
e2) comparing measured P_aO_2 with a predetermined P_aO_2 threshold;
e3) if the measured P_aO_2 does not exceed the predetermined P_aO_2 threshold value, repeating steps c) and d);
e4) if the measured P_aO_2 exceeds the P_aO_2 threshold, comparing the CO_2 content with a first predetermined CO_2 threshold value;
e5) if the CO_2 content exceeds the first predetermined CO_2 threshold value, altering the settings for respiratory rate (RR), positive end expiratory pressure (PEEP), peak inspiratory pressure (PIP) and/or dead space (DS) until the measured CO_2 content no longer exceeds the first predetermined CO_2 threshold value;
e6) if the CO_2 content does not exceed the first predetermined CO_2 threshold value, comparing the CO_2 content with a second predetermined CO_2 threshold value;
e7) if the CO_2 content exceeds the second predetermined CO_2 threshold value, altering the settings of dead space (DS) and/or peak inspiratory pressure (PIP) until the CO_2 content does not exceed the second predetermined CO_2 threshold value or until maximum/minimum values for dead space and PIP are reached;
e8) if the CO_2 content does not exceed the second predetermined CO_2 threshold value, comparing the blood pressure with a predetermined blood pressure interval;
e9) if the measured blood pressure falls within the predetermined blood pressure interval, ending step e);
e10) if the blood pressure falls outside the predetermined blood pressure interval, generating an alarm.